



ETH-1507

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of
ROBERT A. ROUSSEAU

Serial No.: 09/892,340

Confirmation No.: 3554

Filed: June 27, 2001

For: IMPLANTABLE PROSTHETIC
MESH SYSTEM

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

STATE OF NEW JERSEY)
) SS:
COUNTY OF SOMERSET)

Group Art Unit: 3738

Examiner: Crystal M. Gilpin

I hereby certify that this correspondence and/or fee is
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(Date of Deposit)

Deanne M. Bobychuk 11/14/03
(Signature) (Date)

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TECHNOLOGY CENTER R3700

AFFIDAVIT OF ROBERT A. ROUSSEAU UNDER 37 CFR §1.131

Sir:

I, ROBERT A. ROUSSEAU, being duly sworn, deposes and says:

1. I am the sole inventor of all claims of the patent application
identified above and the inventor of the subject matter described and claimed therein.

2. I received a Bachelor of Science in Mechanical Engineering from
the University of Vermont in 1988, and, from about June, 1997 to the present day, I
have been employed at Ethicon, Inc. (hereinafter "Ethicon") of Somerville, New Jersey,
currently as a principal engineer.

3. Since about the year 1998, I have been working in the field of hernia mesh device, having been granted approximately six (6) U.S. patents relating to this field.

4. Prior to July 25, 2000, the filing date of U.S. Patent No. 6,610,006 to Amid et al., I had completed my invention as described and claimed in the subject application in the United States, as evidenced by the following:

5. In the course of my employment at Ethicon, I was asked by Dr. Edward Dormier, my supervisor at Ethicon, to develop a hernia mesh system that can be deployed easily at a hernia site.

6. Further to completing the foregoing task, I conceptualized a solution and expressed various embodiments of this conceptual device in a disclosure, as shown in Exhibit A, attached hereto.

7. Consistent with company practices pertaining to the development of intellectual property by employees, I requested Mr. Jerome Fischer, my co-worker, to review the disclosure shown in Exhibit A with me.

8. I explained the invention shown and described in Exhibit A to Mr. Fischer in terms of its structure, operation and function, and he indicated to me that he understood all the embodiments of the invention shown in Exhibit A. I then requested Mr. Fischer to sign and date the disclosure shown as Exhibit A, which he did. I likewise signed and dated the disclosure.

9. Consistent with company practices for developing products, I sought to prepare prototypes of the hernia mesh device shown in Exhibit A.

10. I directed Mr. Andrew Janetos (President of J-Pac, LLC, an external manufacturing supplier subject to a non-disclosure agreement with Ethicon) to prepare prototypes of the invention depicted in Exhibit A.

11. In response to my directions, Mr. Janetos undertook to make the requested prototypes in the manner described in the present patent application. The prototypes are attached hereto as Exhibit B.

12. I examined the completed prototypes prepared by Mr. Janetos. Based upon my inspection, it appeared that the prototypes conformed to the design shown in Exhibit A and that they would inherently perform their intended function. Based upon my experience and knowledge in the hernia mesh device field, the ridges formed in the prototypes have a rigidity that is not greater than the rigidity of the rest of the prototypes.

13. The prototypes described above were supplied to Dr. Arthur Gilbert, a consulting surgeon under secrecy agreements with Ethicon, for his qualitative review. Dr. Gilbert manipulated the prototypes and passed them through a synthetic hernia model to replicate their anticipated use. Dr. Gilbert was able to bend the prototypes and observe their propensity to return to their original, substantially flat shape from their bent or collapsed shape. Dr. Gilbert was also able to compress the raised ridges formed in the prototypes and observe that they did not interfere with the mesh sheets' ability to conform to a planar shape.

14. All of the events described above in paragraphs 5 through 13 were completed prior to July 25, 2000.

15. My patent application identified in the caption on the first page of this Affidavit discloses and claims the invention depicted in Exhibit A attached hereto, which such invention was reduced to practice by the preparation of a working prototype as set forth above. In particular, I note that independent Claims 1 and 16 of my application is directed to my invention which is shown in Exhibit A.

16. Affiant is competent to testify to the matters stated herein.


Robert A. Rousseau

Sworn and subscribed before me
This 11th day of November, 2003.


Notary Public

ROBERT J. TANNHAUSER
Notary Public Of New Jersey
My Commission Expires 10/18/2004



EXHIBIT A

TITLE PROLENE HERNIA SYSTEM - STIFF UNDERLAY

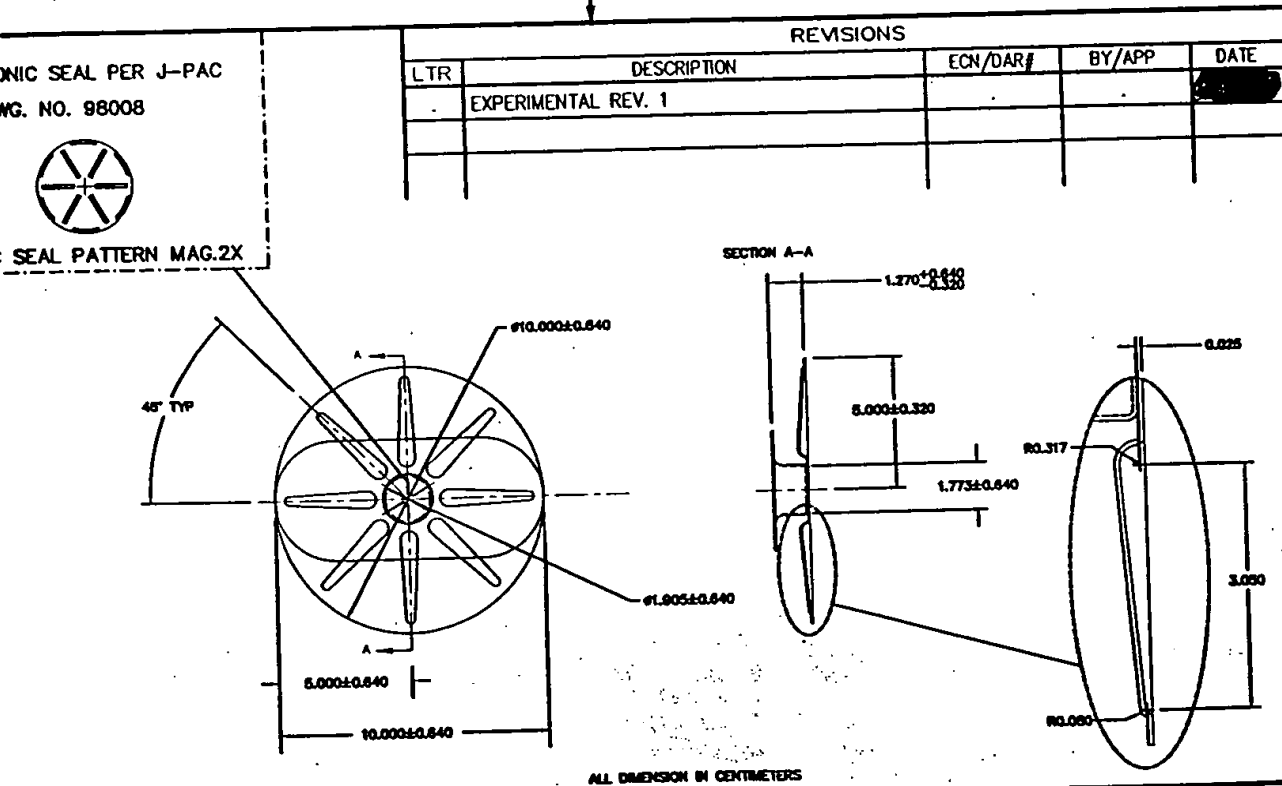
DATE

No. 2443-.73

PURPOSE DOCUMENT IDEAS FOR STIFFENING UNDERLAY PATCH ON PHS

A NEED TO STIFFEN THE PHS UNDERLAY PATCH HAS BEEN COMMUNICATED BY MARKETING AND DR. GILBERT - IDEALLY, THEY WANT SOME MECHANISM TO FACILITATE THE UNDERLAY PATCH SPREADING / DEPLOYING AFTER INSERTION INTO THE HERNIA SITE. THE CONCERN ABOUT RIGIDITY IS THAT IF IT IS TOO RIGID, THE PATIENT MAY HAVE DISCOMFORT. SECONDLY, THE DE LA TORRE PATENT DISCLOSES MESHES WITH ~~STIFFENING~~ SEMI-RIGID STIFFENING ELEMENTS APPLIED OR FORMED INTO THE MESH MATERIAL.

TWO IDEAS ARE ILLUSTRATED. BOTH ENVOKE THE FORMING THE FLAT UNDERLAY PATCH TO HAVE GEOMETRIES WHICH RESIST BENDING WHILE MAINTAINING THE MESH'S NORMAL RIGIDITY. #1 FORMED FINGERS ON UNDERLAY PATCH



UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN INCHES TOLERANCES FRACTIONAL ±1/64 ANGULAR DECIMALS ±.30° JOK ±.01 JOKK ±.005 SURFACE FINISH JOKKK ±.0005 63 CHAMFER ±.20°		CONFIDENTIAL: NOT TO BE REPRODUCED OR USED IN ANY WAY WITHOUT WRITTEN APPROVAL OF ETHICON, INC.		ETHICON, INC. Johnson & Johnson company	
MATERIAL		OWN RAR	DATE	TITLE EXP. PROLENE HERNIA DEVICE 2	
HARDNESS		APP	DATE	DWG NO.	REV E1
FINISH		SCALE NTS	SHT 1 OF 1		


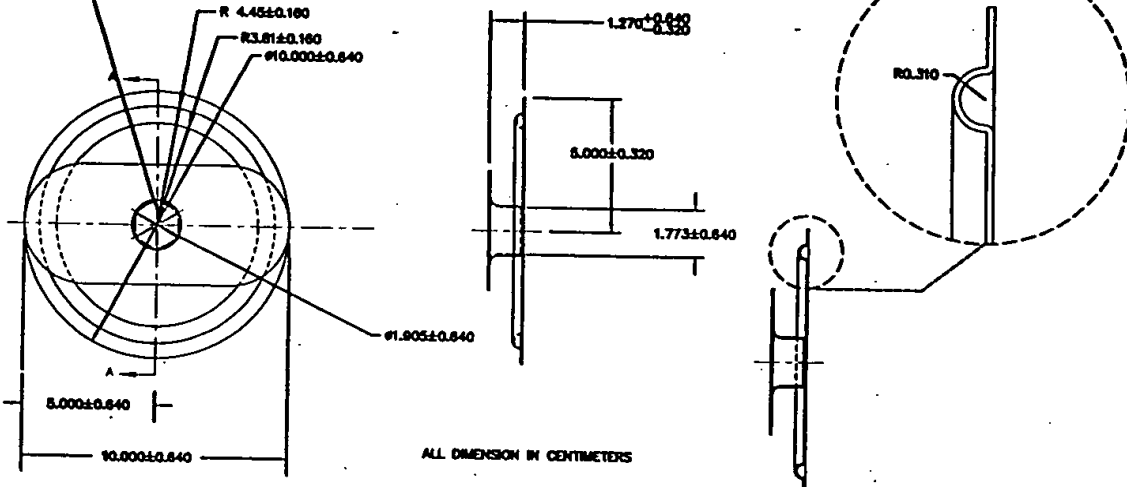
EXPERIMENTER	<i>[Signature]</i>	DATE	<i>[Redacted]</i>
WITNESSED BY	<i>[Signature]</i>	DATE	<i>[Redacted]</i>

o. 2443-74

TITLE PROLENE HERNIA SYSTEM - STIFF UNDERLAY DATE [REDACTED]

PURPOSE CANT. FROM 2443-73

DOCA / SUBODIMENT #2 FURNED RING AROUND CIRCUMFERENCE OF UNDERLAY

<p>SONIC SEAL PER J-PAC DWG. NO. 98008</p>  <p>SONIC SEAL PATTERN MAG.2X</p>	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="5">REVISIONS</th> </tr> <tr> <th>LTR</th> <th>DESCRIPTION</th> <th>ECN/DAR</th> <th>BY/APP</th> <th>DATE</th> </tr> </thead> <tbody> <tr> <td></td> <td>EXPERIMENTAL REV. 1</td> <td></td> <td></td> <td></td> </tr> </tbody> </table>  <p style="text-align: center;">ALL DIMENSION IN CENTIMETERS</p> <p style="text-align: right;">SECTION A-A</p>	REVISIONS					LTR	DESCRIPTION	ECN/DAR	BY/APP	DATE		EXPERIMENTAL REV. 1			
REVISIONS																
LTR	DESCRIPTION	ECN/DAR	BY/APP	DATE												
	EXPERIMENTAL REV. 1															

<p>UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN INCHES TOLERANCES</p> <p>FRACTIONAL ±1/64 ANGULAR ± 30° DECIMALS ±.01 .XX ±.01 .XXX ±.005 SURFACE FINISH .XXXX ±.0005 63 CHAMFER ± 20° ✓</p>	<p>CONFIDENTIAL: NOT TO BE REPRODUCED OR USED IN ANY WAY WITHOUT WRITTEN APPROVAL OF ETHICON, INC.</p> <p>OWN RAR DATE [REDACTED] APP DATE [REDACTED]</p>	<p style="text-align: center;">ETHICON, INC. Johnson & Johnson company</p> <p>TITLE EXP. PROLENE HERNIA DEVICE 1</p> <p>DWG NO. [REDACTED] REV E1</p> <p>SHT 1 OF 1</p>
<p>MATERIAL</p> <p>HARDNESS</p> <p>USED ON</p> <p>APPLICATION</p>	<p>SCALE NTS</p>	

IN BOTH CASES, RIGIDITY IS GAINED FROM THE THREE DIMENSIONAL FURNED STRUCTURE OF THE MESH. THE MESH IN THE STRUCTURE F THE SAME RIGIDITY AS THE MESH IN THE FLAT AREA. THEREFORE, THE STIFFENING FUNCTION IS INTEGRAL TO THE POSITION OF THE MESH SURFACE (SAME AS FOLDING PAPER AND THE TUBES TO BEND AGAINST THE FOLD), I.E. THE MESH IS CONTINUOUS AND THE FURNED 3-D STRUCTURE CAN NOT BE CONSIDERED AS A SEPARATE ELEMENT.

EXPERIMENTER

DATE

WITNESSED BY

DATE